

# IMPACT

2005



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## Assess New Opportunities

Today's biopharma markets are ripe with opportunity. There's little margin for error, and speed is essential. Whether you've discovered a new drug, are contemplating new indications, or need to assess — and value — every possible business option, you're faced with challenges that can make or break any size company. Leveraging a unique mix of experience and expertise, IMS helps clients identify — and successfully address — strategic issues starting as early as clinical trial strategy through the entire product lifecycle. Our experience spans individual molecule and overall portfolio strategy and includes:

- Market/competitive assessment
- Forecasting
- Clinical and regulatory strategy
- Launch planning
- Pricing and reimbursement
- Lifecycle management, consumer health, and mature product strategy
- Corporate strategy & planning
- R&D pipeline management
- Licensing & partnering processes
- Therapeutic area and geographic strategy

Having a comprehensive and current understanding of the global biopharma landscape is essential for making informed decisions that best position your company for the future. To learn how we can help you be more successful, call 310/364-4900.

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## Men's and Women's Issues

Men and women are obviously not built the same. Of course they don't look alike physically, but the way they're built internally is quite different as well. Because of the differences between the sexes, men and women each have unique issues that need to be addressed separately.

## MEN'S ISSUES

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### **Enlarged Prostate (Benign Prostatic Hypertrophy)**

The prostate is the gland that produces the fluid which, together with sperm, makes up semen. Located just below the bladder, it surrounds the urethra (the tube which carries urine from the bladder out of the body). When the prostate becomes enlarged, it squeezes the urethra and makes urination more difficult. It can also press on the bladder, causing a more frequent urge to urinate. Enlarged prostate is fairly common, especially in older men; more than half of men in their sixties have an enlarged prostate, and for men in their seventies and eighties that number jumps to 90 percent. While the exact cause is not known, there are medications to ease the symptoms—95 to 99 percent of people with an enlarged prostate never have any serious complications due to the condition, though problems that do rarely occur are urinary tract infections and kidney damage.

## WOMEN'S ISSUES

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### **Menopause**

All of the changes menopausal women experience are due to declining levels of the hormones estrogen and progesterone. This happens to all women, beginning around age 40, as they shift out of the reproductive stage of their lives. (It can also happen to women of any age who have undergone removal of their ovaries, which produce estrogen and progesterone, or their uterus, which helps regulate the hormones' levels.)

Every woman is affected differently by menopause. Symptoms may include hot flashes, changes in the menstrual cycle, insomnia, mood changes, sexual and urinary problems, and bone loss (which can lead to osteoporosis)—some women may experience many symptoms, others almost none at all. Women who are particularly bothered by any of these things may consider hormone replacement therapy (HRT); this treatment involves taking estrogen and progestin (or only estrogen, for those women who have had their uterus removed), and can help ease symptoms like hot flashes, help prevent uterine cancer, and reduce bone loss. There are some risks involved with extended use, so as with any treatment, the benefits and risks of HRT should be thoroughly discussed with a doctor before beginning.

### **Female Contraception**

Women today have many options available to them today when it comes to birth control. Many of these options involve hormones, and can be oral ("the pill"), implanted (either in the uterus or under the skin), injected, or absorbed (from vaginal devices or patches worn on the skin). Most hormone contraceptives are combinations of estrogen and progesterone, and work in two ways: they prevent the monthly release of an egg from the ovaries, and they thicken the mucous in the cervix and vagina (making it difficult for sperm to get through, just in case an egg is accidentally released). All of these options are reversible—that is, if a woman decides she'd like to become pregnant, she can simply stop using whatever method of contraception she's chosen. There are also permanent methods of preventing pregnancy, known as sterilization. The oldest approved method involves surgically blocking the fallopian tubes, the passage through which eggs move from the ovaries to the uterus. Newer methods do not require surgery, and involve coaxing the body to build up scar tissue to naturally block the fallopian tubes.

PRODUCT	PRODUCER	PARTNER	INDICATION
TUNA System	VidaMed, Inc. (Acquired By Medtronic)	Medtronic, Inc.	Device to help shrink enlarged prostates
Climara Pro	Berlex Inc.		Hormone therapy to alleviate menopausal hot flashes
Essure	Conceptus Inc.		Micro-insert placed into the fallopian tubes, causing tissue growth to block sperm
Levlite	Berlex Inc.		Oral contraceptive
Mirena	Berlex Inc.	Schering AG	Hormone-releasing intrauterine device
Ortho Evra	Cygnus, Inc.	Johnson and Johnson Pharmaceutical Research and Development, LLC, Johnson & Johnson, Ortho-McNeil Pharmaceutical, Inc.	Contraceptive patch
Yasmin	Berlex Inc.	Schering AG	Oral contraceptive